UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/887,464 | 06/22/2001 | Gerard H. Llanos | CRD-0929 | 8413 |

27777 7590 02/12/2003

AUDLEY A. CIAMPORCERO JR.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

| EXAMINER | |
|---|---|
| FERKO, KATHRYN P | |
| ART UNIT | PAPER NUMBER |
| 3743 | |

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/887,464 | Applicant(s) LLANOS ET AL. 3 |
|---|---|---|
| | Examiner Kathryn Ferko | Art Unit 3743 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *9,14 and 18-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-13,15-17 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *18-51* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Response to Amendment*

This is a response to the amendment dated January 13, 2003. Claims 1-8, 10-13, 15-17 and 52 remain pending.

### *Response to Arguments*

1. Applicant's arguments filed January 13, 2003 have been fully considered but they are not persuasive.

Given the broad nature of the term "lubricious," the coating of Ragheb et al. can be considered lubricious for it certainly does not prohibit insertion into the body. Furthermore, the water soluble powder, recited in column 23, lines 31-34 can be considered to prevent the at least one agent from separating from the medical device prior to implantation for the purpose of the coating is timed release. If it allowed the material to separate prior to insertion it would defeat the functional purpose. Although Ragheb et al. do not explicitly recite a silicone-based lubricious coating, there is a prima facie case of obviousness. There is clear prior art teaching to use silicone-based coatings for lubrication purposes and it is well within the scope of the invention to incorporate a lubricant to the stent/delivery system for the purpose of ease of insertion, reduction of friction, and reduction of irritation. For example, see the additional references cited. Ding et al. in US Patent No. 5,837,313 disclose a method of coating a stent with a polymeric silicone material, as discussed in the abstract. See also column 2, lines 60-67, column 3, lines 1-45, column 5, lines 64-67, and column 6, lines 1-2.

Ding et al. in US Patent No. 6,120,536 further discuss coating. Additionally, Reich et al. in US Patent No. 5,993,972 disclose a coating with multiple uses including coating a stent. See the abstract, column 1, lines 30-35, column 3, lines 1-38; column 6, lines 25-50; and column 24, lines 42-51. Moreover, column 26, lines 20-22 state how the coating can be a powder. Furthermore, Cox in US Patent No. 6,375,676 disclose to coat the inner tube of the stent delivery system for the purpose of reducing friction in column 9, lines 58-65.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-8, 10-13, 15-17, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in US Patent No. 6,299,604.

Ragheb et al. disclose a local drug delivery apparatus having a medical device for implantation into a treatment site of a living organism, as recited in column 3, lines 5-22; at least one agent (such as 18) in therapeutic dosages releasably affixed to the medical device for the treatment of reactions by the living organism caused by the medical device or the implantation thereof, as recited in column 3, lines 14-22 and seen in figures 1-3; a material for preventing the at least one agent from separating from the medical device prior to implantation of the medical device at the treatment site, the material being affixed

to at least one of the medical device or a delivery system for the medical device, as recited in column 10, lines 24-67, column 11, lines 1-3, and seen in figure 3; a medical device that is an intraluminal medical device, more specifically a stent, as stated in column 3, lines 6-15; at least one agent that is an anti-proliferative, as stated in column 3, lines 62-65; at least one agent that is an anti-inflammatory, as stated in column 3, lines 62-65; at least one agent that is an anti-coagulant, as stated in column 8, lines 25-37 and column 9, lines 27-60; at least one agent that is an immunosuppressant, as stated in column 9, lines 50-55; at least one agent is a non-viral gene introducer, as stated in column 9, lines 45-47; a material for preventing the at least one agent from separating from the medical device is a lubricious coating, as recited in column 20, lines 63-67, where lubricious coating is incorporated ***onto/into (either via method of application)*** the medical device, as seen in figures 1-3; a lubricious coating is incorporated onto the delivery system for the medical device, as stated in column 18, lines 60-67, column 19, lines 1-20, and column 20, lines 63-67; a material for preventing the at least one agent from separating from the medical device that is a water soluble powder, as stated in column 23, lines 31-34; a water soluble powder is incorporated onto the medical device, as stated in column 23, lines 31-34; water soluble powder that has an anti-oxidant, as recited in column 10, lines 1-3 and column 23, lines 31-34; and a water soluble powder that has an anti-coagulant, as stated in column 8, lines 25-37 and column 23, lines 31-34.

Ragheb et al. disclose the invention as claimed with the exception of a lubricious coating that is a silicone-based material. However, given the versatility of the invention it would fall within the scope, and thus be obvious to one with ordinary skill in the art at the time the invention was made.

***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 12-14, 17, and 28-36 of copending Application No. 09/962,496. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely a broader recitation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 6,120,536; US Patent No. 5,837,313; US Patent No. 5,993,972; and US Patent No. 6,375,676.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Ferko whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KF
February 5, 2003

Henry Bennett
Supervisory Patent Examiner
Group 3700